



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification: A61B 18/14	A1	(11) International Publication Number: WO 00/59393
		(43) International Publication Date: 12 October 2000 (12.10.2000)
(21) International Application Number: PCT/US00/08612		Published
(22) International Filing Date: 31 March 2000 (31.03.2000)		
(30) Priority Data: 09/285,575 02 April 1999 (02.04.1999) US		
(60) Parent Application or Grant GENESIS MEDICAL, INC. [/]; O. EDWARDS, Stuart, D. [/]; O. SWERNOFSKY LAW GROUP ; O.		
(54) Title: TREATING BODY TISSUE BY APPLYING ENERGY AND SUBSTANCES (54) Titre: TRAITEMENT DES TISSUS CORPORELS PAR APPLICATIONS DE SUBSTANCES ET D'ENERGIE		
(57) Abstract		
<p>The invention provides a method and apparatus for treatment for body structures, especially internal body structures involving disorders involving unwanted features or other disorders, that does not require relatively invasive surgery, and is not subject to other drawbacks noted with regard to the known art. A relatively minimally invasive catheter is inserted into the body, treatment of the body structures is applied using the catheter, and the unwanted features or disorders are relatively cured using the applied treatments. The applied treatments can include application of energy or substances, including application of energy (such as of radio frequency energy, microwave energy, or laser or other electromagnetic energy) or substances (such as collagen or other bulking, plumping, or shaping agents; saline or other energy-receiving electrolytes; astringents or other debulking, reducing, or shaping agents; antibiotics or other bioactive, chemoactive, or radioactive compounds). More than one applied treatment can be performed, either in conjunction, in parallel, or seriatim, so as to achieve a combined effect more substantial than any one individual such applied treatment.</p>		
(57) Abrégé		
<p>La présente invention concerne une technique et un appareil permettant de traiter des structures anatomiques, plus particulièrement des structures anatomiques internes sujettes à des troubles, des événements indésirables ou d'autres dysfonctionnements. Cette technique ne nécessite pas de chirurgie relativement invasive, et ne présente aucun des inconvénients généralement rencontrés. On introduit un cathéter relativement peu invasif dans le corps, et on traite les structures anatomiques en utilisant ce cathéter, et les événements indésirables ou les troubles sont relativement soignés par ces traitements. Ces traitements peuvent comprendre l'application d'énergie, telle que celle des fréquences radio, des hautes fréquences, du laser ou une autre énergie électromagnétique, ou l'application de substances telles que le collagène ou d'autres agents étoffants et galbants, des éléments salins ou d'autres électrolytes récepteurs d'énergie, des agents astringents ou d'autres agents amincissants et galbants, des antibiotiques ou d'autres composés bioactifs, chimioactifs ou radioactifs. On peut effectuer plusieurs traitements associés, en parallèle ou en série, de façon à obtenir un effet combiné plus important que l'effet obtenu par l'un quelconque de ces traitements effectué isolément.</p>		

BEST AVAILABLE COPY

PCT

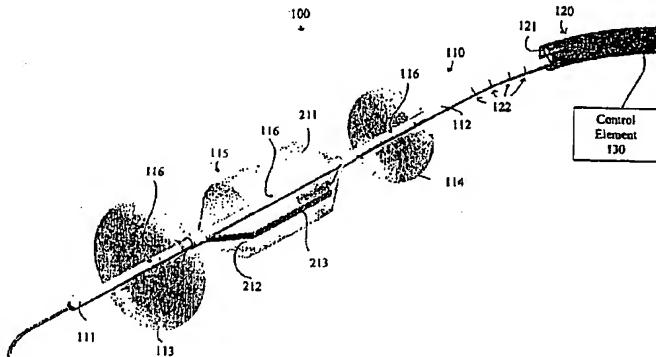
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7: A61B 18/14	A1	(11) International Publication Number: WO 00/59393
		(43) International Publication Date: 12 October 2000 (12.10.00)
<p>(21) International Application Number: PCT/US00/08612</p> <p>(22) International Filing Date: 31 March 2000 (31.03.00)</p> <p>(30) Priority Data: 09/285,575 2 April 1999 (02.04.99) US</p> <p>(71) Applicant: GENESIS MEDICAL, INC. [US/US]; 524 Weddell Drive, #4, Sunnyvale, CA 94089 (US).</p> <p>(72) Inventor: EDWARDS, Stuart, D.; 658 Westridge Drive, Portola Valley, CA 94028 (US).</p> <p>(74) Agent: SWERNOFSKY LAW GROUP; P.O. Box 390013, Mountain View, CA 94039-0013 (US).</p>		
<p>(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>		

(54) Title: TREATING BODY TISSUE BY APPLYING ENERGY AND SUBSTANCES



(57) Abstract

The invention provides a method and apparatus for treatment for body structures, especially internal body structures involving disorders involving unwanted features or other disorders, that does not require relatively invasive surgery, and is not subject to other drawbacks noted with regard to the known art. A relatively minimally invasive catheter is inserted into the body, treatment of the body structures is applied using the catheter, and the unwanted features or disorders are relatively cured using the applied treatments. The applied treatments can include application of energy or substances, including application of energy (such as of radio frequency energy, microwave energy, or laser or other electromagnetic energy) or substances (such as collagen or other bulking, plumping, or shaping agents; saline or other energy-receiving electrolytes; astringents or other debulking, reducing, or shaping agents; antibiotics or other bioactive, chemoactive, or radioactive compounds). More than one applied treatment can be performed, either in conjunction, in parallel, or seriatim, so as to achieve a combined effect more substantial than any one individual such applied treatment.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
DG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
DJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	NL	Netherlands	US	United States of America
CA	Canada	IT	Italy	NO	Norway	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	RO	Romania	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	RU	Russian Federation	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	SD	Sudan		
CM	Cameroon	KR	Republic of Korea	SE	Sweden		
CN	China	KZ	Kazakhstan	SG	Singapore		
CU	Cuba	KL	Saint Lucia				
CZ	Czech Republic	LC	Liechtenstein				
DE	Germany	LI	Sri Lanka				
DK	Denmark	LK	Liberia				
EE	Estonia	LR					

Description

5

10

15

20

25

30

35

40

45

50

55

TREATING BODY TISSUE BY APPLYING ENERGY AND SUBSTANCES

5

Background of the Invention

10

5 1. *Field of the Invention*

This invention relates to treating body tissue, particularly to treating body tissue by altering the shape or volume of that body tissue using energy or substances deployed from an interstitial location in the body.

10

20

2. *Related Art*

Human beings are subject to a number of medical disorders, including those in which a body structure is subject to unwanted features or is otherwise dysfunctional. The body structure can for example include muscular tissue, mucosal tissue, gastro-intestinal tissue, lumen walls, stenotic locations in lumens or interstitial locations, or tumors or other cancerous or precancerous conditions. The unwanted features can for example include being distended or engorged, being unduly large or small, being misshapen, having cysts or tumors, or having undesirable growths. Other dysfunctions can include aneurysms, diverticuli, fissures, hemorrhoids, tumors, or simply an inability for the body structure to perform its proper function.

Medical disorders of these kinds can be particularly acute or discomfiting when they involve important areas of the body, including the cardiovascular system, the gastro-intestinal tract, the genito-urinary system, the pulmonary system, the vascular system, or other body systems. For a first example, disorders involving body structures in the gastro-intestinal tract can lead (at a first end thereof) to inadequate operation of the esophageal sphincter, to gastro-intestinal reflux, or to Barrett's condition. For a second example, disorders involving body structures in the gastro-intestinal tract can lead (at a second end thereof) to fecal or urinary incontinence.

50

55

5 One problem in the known art is that treatment of such disorders can involve relatively invasive and labor-intensive surgery. This has the drawbacks of incurring relatively high expense, of incurring relatively high risk (in some cases) of damage to important nerves, and of producing iatrogenic effects that are relatively hazardous to
10
15 the patient.

Accordingly, it would be advantageous to provide a method and apparatus for treatment for body structures, especially internal body structures involving unwanted features or other disorders, that does not require relatively invasive surgery,
10 and is not subject to other drawbacks noted with regard to the known art. This advantage is achieved in an embodiment of the invention in which a relatively minimally invasive catheter is inserted into the body, treatment of the body structures is applied using the catheter, and the unwanted features or disorders are relatively cured using the applied treatments. The applied treatments can include application of energy or substances, including application of energy (such as of radio frequency energy, microwave energy, or laser or other electromagnetic energy) or substances (such as collagen or other bulking, plumping, or shaping agents; saline or other energy-receiving electrolytes; astringents or other debulking, reducing, or shaping agents; antibiotics or other bioactive, chemoactive, or radioactive compounds). More than one applied treatment
20 can be performed, either in conjunction, in parallel, or seriatim, so as to achieve a combined effect more substantial than any one individual such applied treatment.
25
30
35

Summary of the Invention

40 The invention provides a method and system for treatment for body structures, especially internal body structures involving unwanted features or other disorders, that does not require relatively invasive surgery, and is not subject to other
45 drawbacks noted with regard to the known art. A relatively minimally invasive catheter is inserted into the body, treatment of the body structures is applied using the catheter, and the unwanted features or disorders are relatively cured using the applied
30 treatments.
50

5

In a preferred embodiment, the applied treatments can include application of energy or substances, including application of energy (such as of radio frequency energy, microwave energy, or laser or other electromagnetic energy) or substances (such as collagen or other bulking, plumping, or shaping agents; saline or other energy-receiving electrolytes; astringents or other debulking, reducing, or shaping agents; antibiotics or other bioactive, chemoactive, or radioactive compounds).

15

In a preferred embodiment, more than one applied treatment can be performed, either in conjunction, in parallel, or seriatim, so as to achieve a combined effect more substantial than any one individual such applied treatment.

20

In preferred embodiments, the unwanted features or other disorders include one or more of the following:

25

15

o Barrett's disease, other growths on the esophageal lining or near the esophageal sphincter, or otherwise at an ingestive end of the gastro-intestinal system;

30

20

o fecal incontinence or other failures of the musculature or sphincters at an excretory end of the gastro-intestinal system;

35

or

o urinary incontinence or other failures of the musculature or sphincters at an excretory end of the gastro-intestinal system.

40

25

Brief Description of the Drawings

45

Figure 1 shows a drawing of a first device for treatment of a body structure, for possible application to body structures at an ingestive end of the gastro-intestinal system.

50

55

5 Figure 2 shows a drawing of the first device for treatment of a body structure, as possibly positioned at or near an esophageal sphincter.

10 Figure 3 shows a drawing of a second device for treatment of a body structure, for possible application to body structures at an excretory end of the gastro-intestinal system.

15 Figure 4 shows a drawing of the second device for treatment of a body structure, as possibly positioned at or near a rectal sphincter.

20 Figure 5 shows a drawing of the second device for treatment of a body structure, as possibly positioned at or near a urinary sphincter.

25 Detailed Description of the Preferred Embodiment

15 In the following description, a preferred embodiment of the invention is described with regard to preferred process steps and data structures. Those skilled in the art would recognize after perusal of this application that embodiments of the invention can be implemented using processors or circuits adapted to particular process steps and data structures described herein, and that implementation of the process steps and data structures described herein would not require undue experimentation or further invention.

40 *First Treatment Device*

25 Figure 1 shows a drawing of a first device for treatment of a body structure, for possible application to body structures at an ingestive end of the gastro-intestinal system.

5 A device 100 includes a catheter 110, the catheter 110 having a distal end 111, a proximal end 112, a distal balloon 113, a proximal balloon 114, a treatment structure 115, and a set of aspiration or delivery elements 116.

10 The distal end 111 is disposed for insertion into a cavity of the body. In 5 a preferred embodiment, the cavity can include a section of the gastro-intestinal tract of the body. In alternative embodiments, the cavity may include one or more of, or some 15 combination of, the following.

10 o Any portion of the bronchial system, the cardiovascular system, the genito-
20 urinary tract, the lymphatic system, the pulmonary system, the vascular system,
 or other systems in the body;

25 o Any biologic conduit or tube, such as a biologic lumen that is patent or one that
15 is subject to a stricture;

30 o Any biologic cavity or space, such as a cyst, a gland, a layered structure or
 striation, or a medical device implanted or inserted in the body;

35 o Any biologic operational structure, such as a gland, or a muscular or other organ
 (such as the colon, the diaphragm, the heart, a kidney, a lung, the rectum, an in-
 voluntary or voluntary sphincter);

40 o Any other biologic structure, such as a herniated body structure, a set of dis-
25 eased cells, a set of displasic cells, a surface of a body structure (such as the
 sclera), a tumor, or a layer of cells (such as fat, muscle, or skin).

45 The proximal end 112 is disposed for coupling to a medical device 120.
In a preferred embodiment, the medical device 120 can include a device for insertion
50 30 and probing into the body, such as a colonoscope, an endoscope, or another type of
 catheter. The medical device 120 is preferably controlled from a location outside the

.5 body, such as an instrument in an operating room or an external device for manipulating the inserted catheter 110.

10 For example, in a preferred embodiment in which the medical device 120 includes an endoscope, the device 110 can be coupled to one of a plurality of lumens 121 in the medical device 120 for sensing, for delivery or aspiration of substances, or for delivery of energy. For example, one or more of the lumens 121 can include an optical wave-guide, a delivery path for antibiotics or saline, an aspiration path for liquids or killed cells, or a delivery path for electromagnetic energy.

15 10 In alternative embodiments, the medical device 120 may include a device that is implanted into the body, or is inserted into the body and manipulated from inside or outside the body during a medical procedure. For example, the medical device 120 can include a programmed AICD (artificial implanted cardiac defibrillator), a programmed glandular substitute (such as an artificial pancreas), or a medical device 120 for use during surgery or in conjunction with other medical procedures.

25 30 20 35 In a preferred embodiment, the medical device 120 is coupled to a control element 130, by which medical or other personnel can control operation of the medical device 120, and of the catheter 110. Such control can include aspiration or delivery of substances, or delivery or sensing of energy.

40 25 45 The distal balloon 113 is disposed for inflation, preferably after the catheter 110 has been inserted into the body. The distal balloon 113 can be disposed with regard to the catheter 110 in conjunction with markings 121 on or near the proximal end 112, so that medical or other personnel can determine a distance the distal end 111 has penetrated within the body. For example, in a preferred embodiment in which the in which the catheter 110 is inserted into the rectum for treatment of incontinence, the markings 121 can be used to determine that distance.

5 The inflated distal balloon 113 can perform one or more of, or some
combination of, the following functions:

10 o The distal balloon 113 can position the catheter 110 in a relatively fixed posi-
5 tion within the body. For example, in a preferred embodiment in which the
catheter 110 is inserted into the urethra, the inflated distal balloon 113 can pre-
vent the catheter 110 from being pulled back out of the urethral canal.

15 o The distal balloon 113 can isolate the catheter 110 (and its treatment structure
10 115) from the rest of the body. For example, in a preferred embodiment in
which the catheter 110 is inserted into the rectum, the inflated distal balloon 113
20 can prevent treatment substances and any substances that result from treatment
(such as killed cells) from passing into other regions of the body.

25 15 o The distal balloon 113 can serve as a sensor. For example, the distal balloon
113 can include an x-ray opaque element or an x-ray reflector, so as to enable
medical or other personnel to determine a position of the catheter 110 using a
30 fluoroscope or an x-ray device.

20 20 o The distal balloon 113 can serve as a delivery element for electromagnetic en-
35 ergy. For example, the distal balloon 113 can include a set of metallic (or me-
tallic coated) elements, or can be coupled to a basket having a set of electrodes,
for delivery of RF or other electromagnetic energy.

40 25 In a preferred embodiment in which the distal balloon 113 is used as a
delivery element for electromagnetic energy, the distal balloon 113 is spherical (or el-
lipsoidal) and conceptually divided into a set of eight octants (each preferably a
45 semidemihemisphere). Each octant can be separately activated to deliver electromag-
netic energy to selected body structures near the distal balloon 113.

30

50

55

5 In a preferred embodiment in which the distal balloon 113 is used as a
delivery element for electromagnetic energy, the distal balloon 113 includes a micropo-
rous or otherwise partially porous membrane, so that saline or another substance can be
exuded from the distal balloon 113. The saline or other substance are preferably used
10 to pre-condition tissue for reception of the electromagnetic energy, or to receive that
electromagnetic energy itself. For example, in a preferred embodiment, the distal bal-
loon 113 exudes about 10% saline and delivers about 460 kilohertz RF energy using
15 the saline as a receiving antenna.

10 Delivery of RF or other electromagnetic energy is described in further
20 detail herein below.

25 Similarly, the proximal balloon 114 is also disposed for inflation. The
proximal balloon 114 can also be disposed with regard to the catheter 110 in conjunc-
15 tion with markings 121 on or near the proximal end 112, so that medical or other per-
sonnel can determine a distance the distal end 111 has penetrated within the body.

30 Similarly, the inflated proximal balloon 114 can perform one or more of,
or some combination of, the following functions:

20

35 o The proximal balloon 114 can position the catheter 110 in a relatively fixed po-
sition within the body. For example, in a preferred embodiment in which the
catheter 110 is inserted into the urethra, the inflated proximal balloon 114 can
prevent the catheter 110 from being inserted further into the urethral canal.

40

25 o The proximal balloon 114 can isolate the catheter 110 (and its treatment struc-
ture 115) from the rest of the body. For example, in a preferred embodiment in
45 which the catheter 110 is inserted into the esophagus, the inflated proximal
balloon 114 can prevent treatment substances and any substances that result
30 from treatment (such as killed cells) from passing into other regions of the body.

50

5 o The proximal balloon 114 can serve as a sensor. For example, the proximal balloon 114 can include an x-ray opaque element or an x-ray reflector, so as to enable medical or other personnel to determine a position of the catheter 110 using a fluoroscope or an x-ray device.

10 5 o The proximal balloon 114 can serve as a delivery element for electromagnetic energy. For example, the proximal balloon 114 can include a set of metallic (or metallic coated) elements, or can be coupled to a basket having a set of electrodes, for delivery of RF or other electromagnetic energy.

10

20 The treatment structure 115 includes a shaped balloon, having a cylindrical shape with an indentation, and having a treatment element disposed in the indentation. The treatment structure 115 is further described with regard to figure 2.

25

15

30 The aspiration or delivery elements 116 include a set of holes or other passages, through which substances can be exuded or flowed. For aspiration, the aspiration or delivery elements 116 can be coupled to a pump or other suction element, so as to generate suction to drain flowable material from the body. For delivery, the aspiration or delivery elements 116 can be coupled to a pump or other pressure element, 20 and to a source of flowable substances, so as to generate pressure to source flowable material into the body.

35

Treatment Device Used for Esophagus

40

25

Figure 2 shows a drawing of the first device for treatment of a body structure, as possibly positioned at or near an esophageal sphincter.

45

30

The catheter 110 is inserted into the body and disposed so that the treatment structure 115 is located at or near a region between the esophagus 201 and an esophageal sphincter 202 (between the esophagus 201 to the stomach 203).

50

55

5 The treatment structure 115 includes a shaped balloon 211, having a cylindrical shape with an indentation 212, and having a treatment element 213 disposed in the indentation 212.

10 5 Disposed in the body, the shaped balloon 211 substantially fills the region of the esophagus 201 near the esophageal sphincter 202. The shaped balloon 211 thus isolates a mucosal surface of the esophagus 201 from treatment, except for a region defined by the indentation 212.

15 10 The region defined by the indentation 212 includes a portion of the mucosal surface area of the esophagus 201, which portion is selected for treatment. In an embodiment used to treat Barrett's, a portion is selected for treatment that has cells foreign to a normal esophagus 201 (such as cells like those of the stomach lining, dysplastic cells, or pre-cancerous cells). In a preferred embodiment, the portion selected for treatment includes no more than a 90-degree arc of a cross-section of the esophagus 201, and preferably no more than a 45-degree arc. The indentation 212 is no more than 90 degrees of arc, and preferably no more than 45 degrees of arc.

20 25 30 The treatment element 213 includes a set of treatment points 214, each coupled using a separate controller 215 to the medical device 120 or to the control element 130. In a preferred embodiment, each treatment point 214 can be separately controlled using the control element 130 so as to select a variable length portion of the esophagus 201 for treatment.

35 40 25 The indentation 212 and the treatment element 213 can be rotated with the device 100 so as to select a second portion of the mucosal surface area of the esophagus 201 for treatment. In a preferred embodiment, the second portion of the mucosal surface area of the esophagus 201 is selected only after a first portion of the mucosal surface area of the esophagus 201 has been treated and given time to heal.

45 30 50 The indentation 212 and the treatment element 213 can be rotated with the device 100 so as to select a second portion of the mucosal surface area of the esophagus 201 for treatment. In a preferred embodiment, the second portion of the mucosal surface area of the esophagus 201 is selected only after a first portion of the mucosal surface area of the esophagus 201 has been treated and given time to heal.

The treatment points 214 each include unipolar RF (radio frequency) electrodes, each of which can operate to treat tissue by ablation, cell death, desiccation, or other aspects of delivery of RF energy to tissue. In a preferred embodiment, the shaped balloon 211 can be expanded and filled using relatively cold saline, so that the surface of the esophagus 201 isolated by the shaped balloon 211 can be kept at a relatively lower temperature during treatment.

In alternative embodiments, the treatment points 214 can be disposed to treat tissue using other techniques, such as by emission of other forms of energy or by emission of substances. These can include one or more of, or some combination of, any of the following:

- o bipolar RF electrodes;
- o chemical treatment, such as acid, antibiotics, enzymes, or other bioactive, chemooactive, or radioactive substances;
- o heat, such as using heated saline or other heated substances;
- o infrared energy, such as from an infrared laser or a diode laser;
- o microwave energy, such as electromagnetic energy in the about 915 megahertz to about 2.45 gigahertz range;
- o optical energy, such as from a laser;
- o other electromagnetic energy, including direct current or ELF (extremely low frequency);

5 o physical treatment, such as crushing using an expandible balloon, scraping using an attachment to an expandible balloon, or another physical treatment technique;

10 5 or

 o sonic energy, including ultrasound.

15 In a preferred embodiment, the treatment points 214 can also be disposed to pre-condition or pre-treat tissue so as to be conditioned, sensitized, or otherwise prepared for treatment. In a preferred embodiment, the pre-treatment includes exuding saline for absorption into the treated tissue. The absorbed saline acts to enhance reception of electromagnetic (particularly RF) energy by the tissue.

25 In alternative embodiments, the treatment points 214 can be disposed to pre-condition or pre-treat tissue using other techniques, such as by emission of other forms of energy or by emission of other substances. These can include any of the forms of energy or substances used for treatment, and can also include one or more of, or some combination of, any of the following:

30 20 o a bulking, plumping, or supportive agent, such as a collagen, a gel, or a stent;

35 25 o a debulking, deplumping, or astringent or restrictive agent, such as an acid, an enzyme, or a physical constraint such as an elastic or wire;

40 40 25 or

 o a shaping or reshaping agent, such as a cutting element or a stent.

45 In a preferred embodiment, the treatment points 214 can also be disposed to post-condition or post-treat tissue so as to be healed or otherwise repaired after treatment. In a preferred embodiment, the post-treatment includes exuding analgesic, antibiotic, or anti-inflammatory agents, for absorption into the treated tissue, and tissue

5 nearby. The post-treatment acts to enhance the ability of the treated tissue, and tissue
nearby, to recover from treatment.

10 In alternative embodiments, the treatment points 214 can be disposed to
5 post-condition or post-treat tissue using other techniques, such as by emission of other
forms of energy or by emission of other substances.

15 *Second Treatment Device*

10 Figure 3 shows a drawing of a second device for treatment of a body
20 structure, for possible application to body structures at an excretory end of the gastro-
intestinal system.

25 A device 300 includes a catheter 310 and a control element 320.

15

The catheter 310 includes a distal end 311, a proximal end 312, and a
treatment structure 313.

30

20 The distal end 311 and the proximal end 312 of the catheter are similar to
the distal end 111 and proximal end 112 described with regard to figure 1.

35

The treatment structure 313 includes an inflatable/deflatable structure
314, a set of treatment elements 315, and a set of treatment element extrusion ports
316.

40

25 The inflatable/deflatable structure 314 includes a balloon disposed within
45 a flexible basket, so that when the balloon is inflated or deflated, the flexible basket is
expanded or contracted. In a preferred embodiment, the balloon is at least partially
microporous or porous, so that flowable substances used to expand or fill the balloon
30 can be exuded from the balloon into surrounding tissue.

50

55

5 The treatment elements 315 include electrodes, physically coupled to the control element 320, and disposed for extrusion using the treatment element extrusion ports 316.

10 5 The treatment element extrusion ports 316 include holes or other passageways in the flexible basket, so the electrodes can be extruded therethrough.

15 10 The electrodes are substantially curved, so that in a non-extruded state the electrodes are disposed within the flexible basket, and that in an extruded state the electrodes are disposed outside the flexible basket at a substantial angle to the direction at which the electrodes are extruded. The electrodes preferably have sufficient length and curve so that the substantial angle exceeds about 60 degrees of arc, and can exceed 20 180 degrees of arc from the direction at which the electrodes are extruded.

25 15 The control element 320 includes a handle 321, an inflation/deflation port 322, an electrode extrusion control 323, a set of substance aspiration or deployment ports 324, and an electrical energy port 325.

30 20 The handle 321 is disposed for manipulation by medical or other personnel, and can be shaped for being held in the hand.

35 35 The inflation/deflation port 322 includes a receptor for coupling to a source of air, liquid, or other flowable substance. The flowable substance inflates the treatment structure 313 when input to the inflation/deflation port 322, and deflates the 40 40 treatment structure 313 when output from the inflation/deflation port 322.

45 45 The electrode extrusion control 323 includes a control element for controlling the amount of extrusion of electrodes from the treatment structure 313.

5 The substance aspiration or deployment ports 324 include receptors for aspirating flowable substances from or from near the treatment structure 313, and for deploying flowable substances into or near to the treatment structure 313.

10 5 The electrical energy port 325 includes a conductive element that can be coupled to a source of electrical energy, such as a battery, a generator, or a wall socket.

15 *Treatment Device Used for Fecal Incontinence*

10 Figure 4 shows a drawing of the second device for treatment of a body structure, as possibly positioned at or near a rectal sphincter.

20 25 The device 300 is positioned at or near the rectum, preferably in a region of relatively insensate tissue 410 between the involuntary sphincter 420 and the voluntary sphincter 430.

30 35 In operation, the treatment elements 315 are extruded into the relatively insensate tissue 410. The treatment elements 315 apply pre-conditioning, treatment, and post-treatment to the relatively insensate tissue 410 and to internal tissue 411 located beneath the relatively insensate tissue 410.

40 45 The treatment elements 315 operate to perform ablation or debulking, to perform bulking or plumping, or otherwise to perform shaping or reshaping, of the relatively insensate tissue 410 and the internal tissue 411. After operation, the rectum (either the involuntary sphincter 420 or the voluntary sphincter 430 or both) are capable of a more tightly sealed closure, so as to militate against fecal incontinence.

45 *Treatment Device Used for Urinary Incontinence*

30 35 Figure 5 shows a drawing of the second device for treatment of a body structure, as possibly positioned at or near a urinary sphincter.

5

10

The device 300 is positioned at or near a urinary sphincter 510. In operation, a distal balloon (like that of the first device 100) is positioned at an exit point of the bladder 520. Inflated, the distal balloon prevents the device 300 from being 5 mistakenly drawn out of the urethra 530.

15

In operation, the inflatable/deflatable structure 314 has a substantially greater length-to-width ratio, so as to fit into the urethra 530.

20

In operation, the treatment elements 315 are extruded into the surface of the urethra 530, and possibly into tissue there-behind. The treatment elements 315 apply pre-conditioning, treatment, and post-treatment to those tissues.

25

The treatment elements 315 operate to perform ablation or debulking, to 15 perform bulking or plumping, or otherwise to perform shaping or reshaping, of those tissues. After operation, the urinary sphincter 510 and the urethra 530 are capable of a more tightly sealed closure, so as to militate against urinary incontinence.

30

Generality of the Invention

20

The invention has substantial generality of application to various fields 35 for biopsy or treatment of medical conditions. These various fields include, one or more of, or a combination of, any of the following (or any related fields):

40

25

As noted above, the invention can be used in any area of the body, including the biologic systems and locations noted herein. The invention can be used for the general purpose of reducing, plumping, or reshaping body structures, tissues, or regions of the body otherwise empty (or filled with biologic substances).

45

30

For examples, the invention can be used in one or more of, or some combination of, the following:

50

55

5 o In the head and neck, such as the cheeks, eyes, throat, larynx, or other structures;

10 5 o For the purpose of reforming damaged body parts, for the purpose of reshaping misshapen body parts, or for cosmetic effects;

15 or

10 o For the purpose of replacing the volume filled by body parts that are missing, whether due to congenital defect, infection, or surgery.

20 *Alternative Embodiments*

25 Although preferred embodiments are disclosed herein, many variations are possible which remain within the concept, scope, and spirit of the invention, and
15 these variations would become clear to those skilled in the art after perusal of this application.

30

35

40

45

50

55

Claims

5

10

15

20

25

30

35

40

45

50

55

5

Claims

10

1. A method including steps for
positioning a medical device substantially within a body of a patient, said
medical device including (a) a catheter having a first element for emitting a flowable
substance, and (b) a second element for affecting said flowable substance so as to af-
fect tissue near said flowable substance; and
15 pre-conditioning selected tissue for a treatment using said first element
and second element.

10

20

2. A method as in claim 1, including steps for post-treating said 'se-
lected tissue in response to a treatment using said first element and second element.

25

3. A method as in claim 1, wherein said selected tissue is subject to

15 Barrett's condition.

30

4. A method as in claim 1, wherein said second element includes a
plurality of substantially differing frequencies of electromagnetic energy.

35

5. A method as in claim 4, wherein said differing frequencies in-
clude at least two of: radio frequency energy, microwave energy, and visible light.

40

6. A method as in claim 1, wherein said selected tissue is substan-
tially near an sphincter.

25

7. A method as in claim 6, wherein said sphincter is a rectal sphinc-
ter.

45

8. A method as in claim 6, wherein said sphincter is a urinary
30 sphincter.

50

55

5 9. A method as in claim 6, wherein said sphincter is an esophageal
sphincter.

10 10. A method as in claim 1, wherein said selected tissue is treated to
5 affect a condition of incontinence.

15 11. A method as in claim 10, whercin said condition of incontinence
includes fecal incontinence.

10 12. A method as in claim 10, wherein said condition of incontinence
20 includes urinary incontinence.

25

30

35

40

45

50

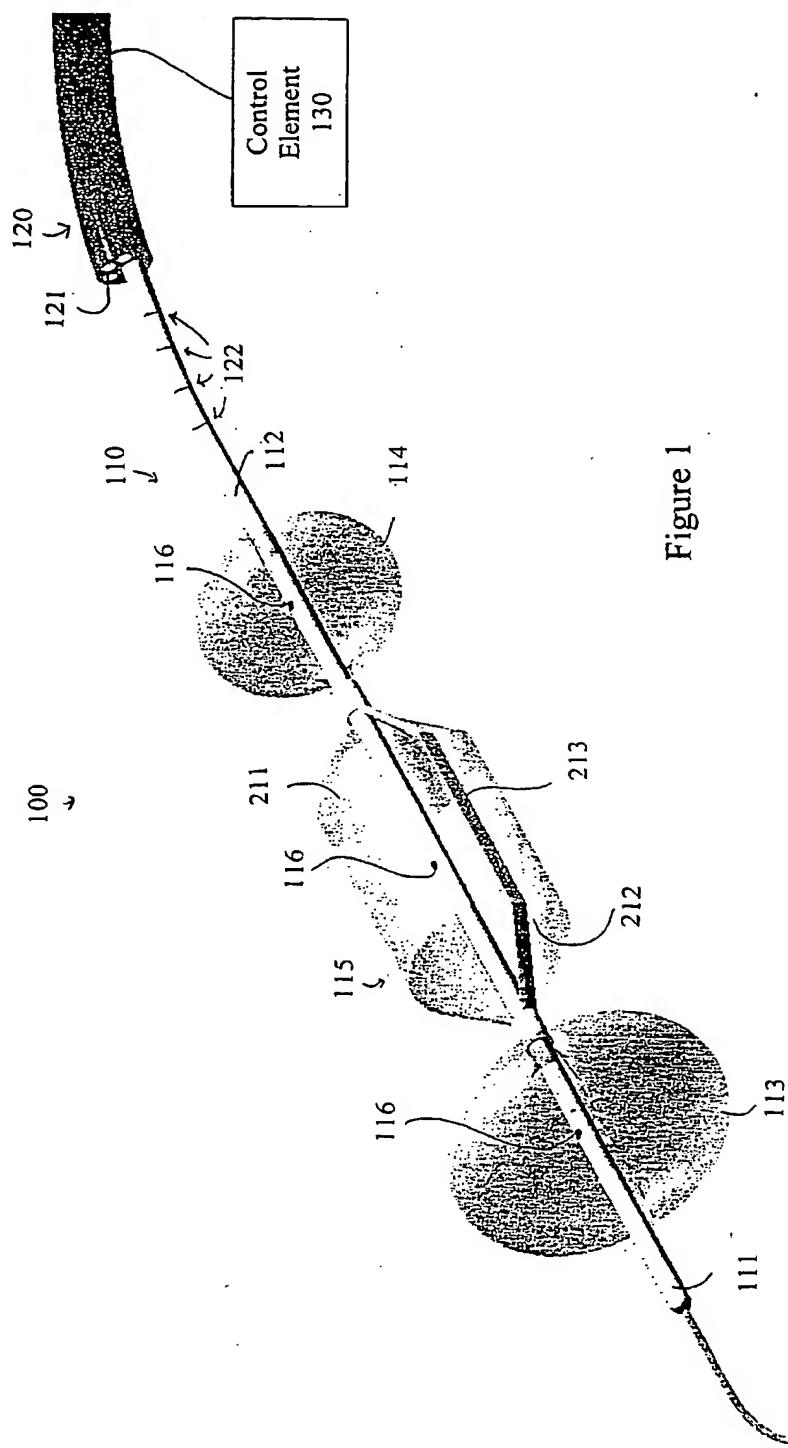


Figure 1

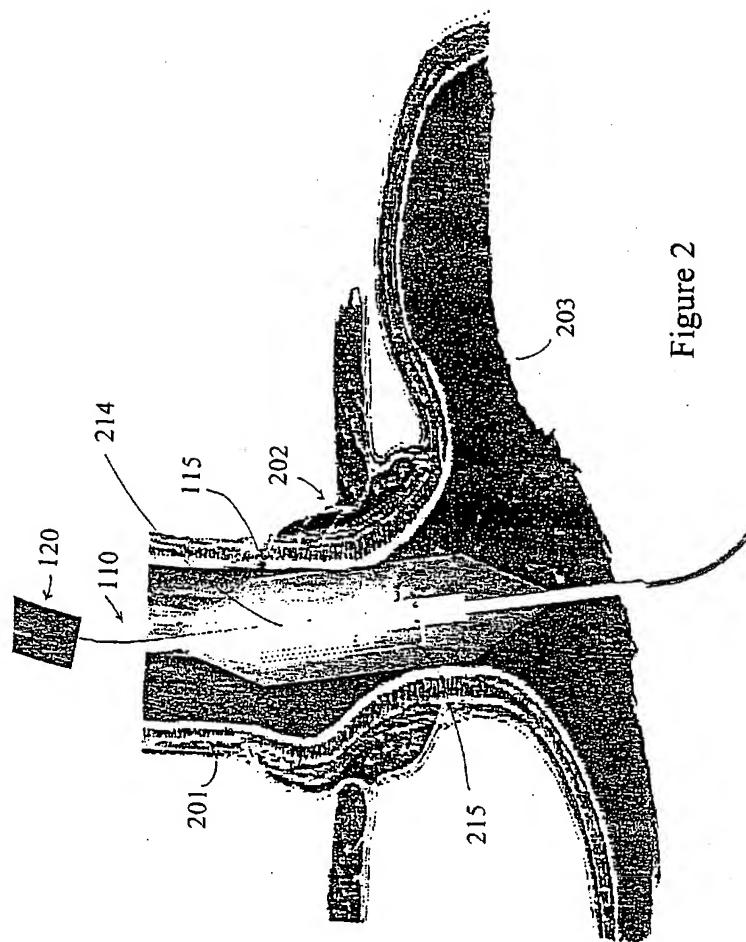


Figure 2

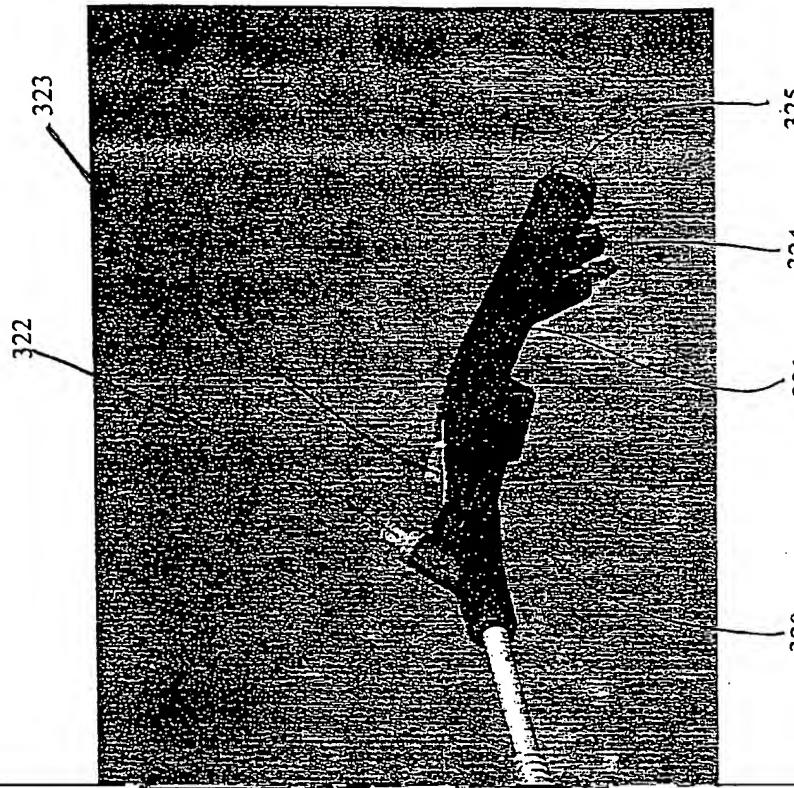


Figure 3

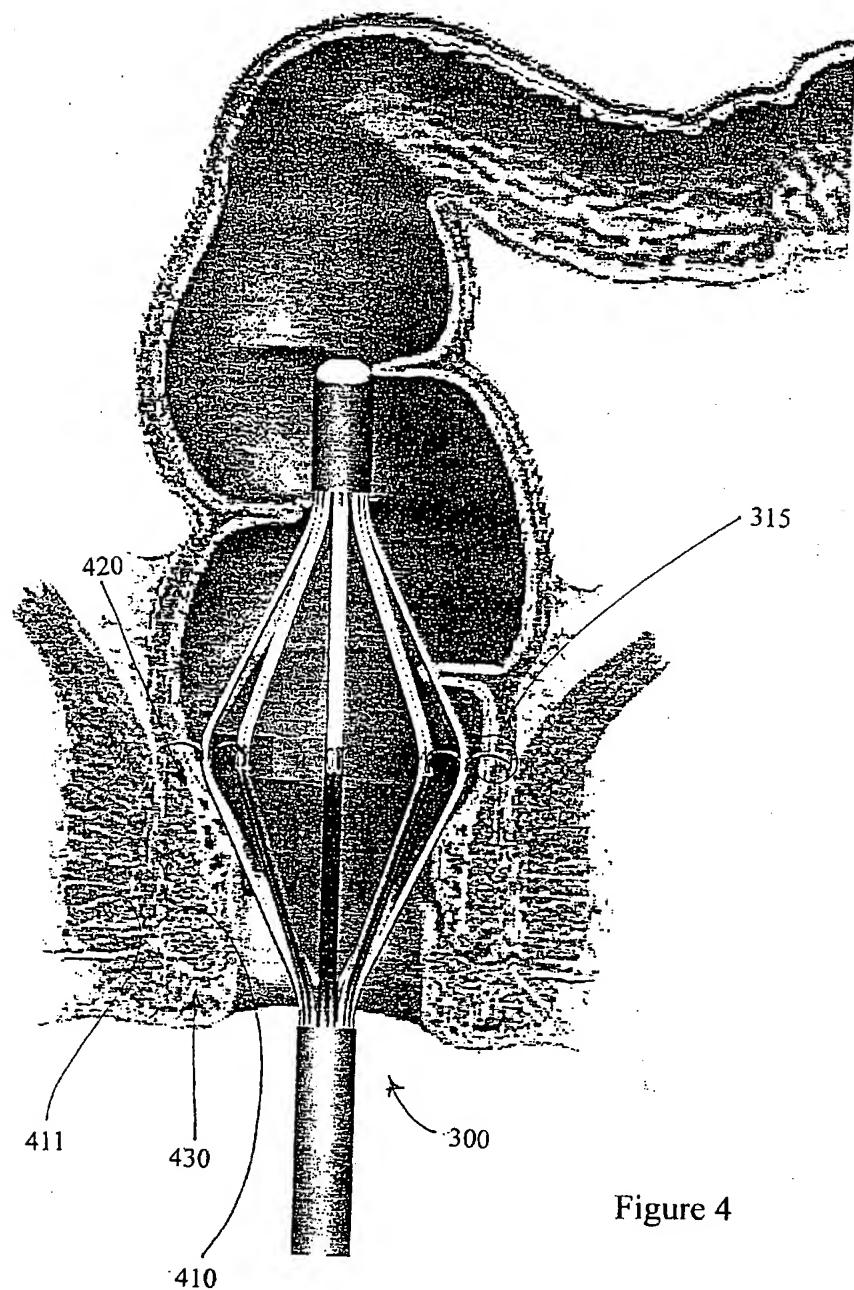


Figure 4

Urethra of Female
Frontal Section

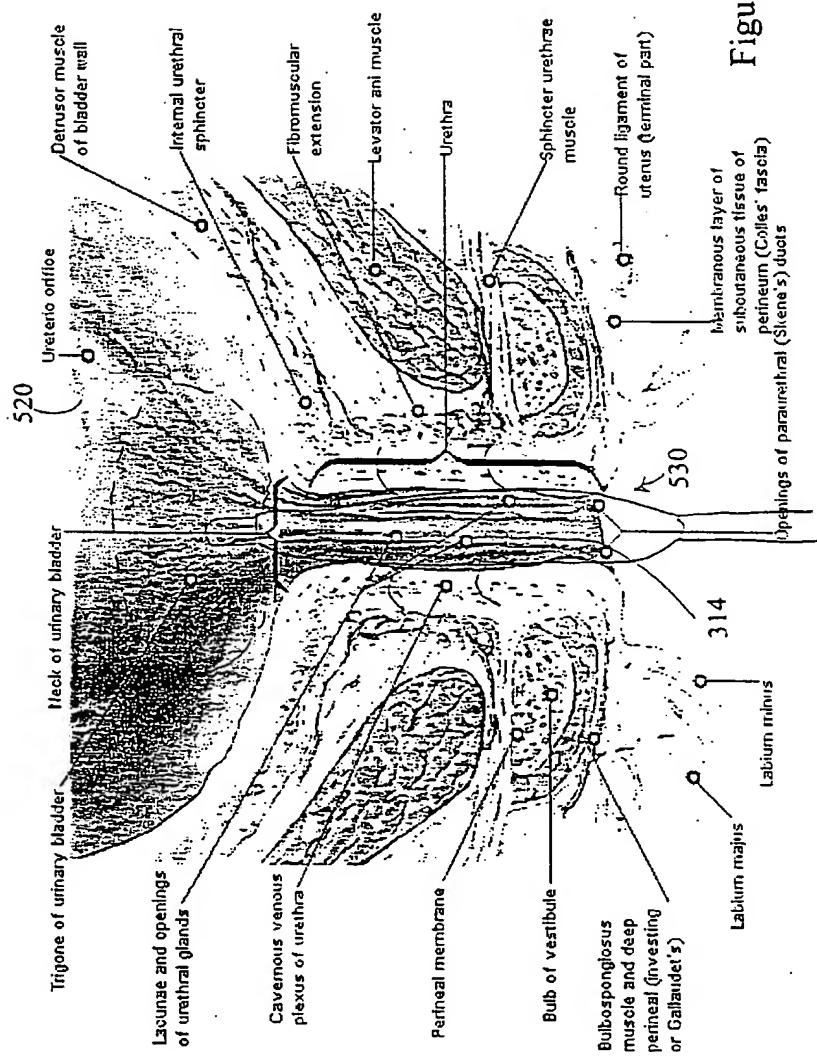


Figure 5

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 00/08612

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B18/14		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 591 125 A (LUNDQUIST INGEMAR H ET AL) 7 January 1997 (1997-01-07) see column 5 lines 15-25	
P, A	WO 99 42044 A (CONWAY STUART MEDICAL INC ; EDWARDS STUART D (US)) 26 August 1999 (1999-08-26)	
A	WO 99 03413 A (VNUS MEDICAL TECHNOLOGIES INC) 28 January 1999 (1999-01-28)	
A	US 5 575 788 A (BAKER JAMES ET AL) 19 November 1996 (1996-11-19)	
<input type="checkbox"/> Further documents are listed in the continuation of box C.		<input checked="" type="checkbox"/> Patent family members are listed in annex.
* Special categories of cited documents :		
A document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubt on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed		
T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art *S* document member of the same patent family		
Date of the actual completion of the international search	Date of mailing of the international search report	
12 July 2000	18/07/2000	
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentdaan 2 NL - 2280 HV Rijswijk Tel: (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Papone, F	

INTERNATIONAL SEARCH REPORT

Information on patent family members

Title	International Application No
PCT/US 00/08612	

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
US 5591125 A	07-01-1997	US 5421819 A US 5370675 A US 5895370 A AU 685086 B AU 6133194 A AU 718834 B AU 6189698 A AU 687813 B AU 6819094 A CA 2155217 A CA 2162724 A CN 1125390 A DE 4416840 A DE 69423814 D EP 0628288 A EP 0631514 A FR 2705241 A IL 108532 A IL 109545 A JP 8506259 T JP 8510148 T WO 9417856 A WO 9426186 A US 5409453 A US 5486161 A US 5556377 A US 5720718 A US 5542915 A US 5470309 A US 5554110 A US 5549644 A US 5456662 A US 5514131 A US 5720719 A US 5667488 A US 5531677 A US 5685839 A US 5582589 A US 5599295 A US 5741225 A US 5718702 A US 5848986 A US 5762626 A US 5807309 A AT 132046 T AU 671405 B AU 2047595 A AU 657235 B AU 4999893 A BR 9306893 A	06-06-1995 06-12-1994 20-04-1999 15-01-1998 29-08-1994 20-04-2000 09-07-1998 05-03-1998 12-12-1994 18-08-1994 24-11-1994 26-06-1996 17-11-1994 11-05-2000 14-12-1994 04-01-1995 25-11-1994 13-07-1997 24-09-1998 09-07-1996 29-10-1996 18-08-1994 24-11-1994 25-04-1995 23-01-1996 17-09-1996 24-02-1998 06-08-1996 28-11-1995 10-09-1996 27-08-1996 10-10-1995 07-05-1996 24-02-1998 16-09-1997 02-07-1996 11-11-1997 10-12-1996 04-02-1997 21-04-1998 17-02-1998 15-12-1998 09-06-1998 15-09-1998 15-01-1996 22-08-1996 10-08-1995 02-03-1995 15-03-1994 08-12-1998	
WO 9942044 A	26-08-1999	US 6056744 A AU 2778899 A	02-05-2000 06-09-1999	
WO 9903413 A	28-01-1999	AU 8412498 A EP 0996379 A	10-02-1999 03-05-2000	
US 5575788 A	19-11-1996	US 5558672 A	24-09-1996	

Form PCT/ISA/210 (patent family annex) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte	rnai Application No
PCT/US 00/08612	

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5575788 A		US 5569241 A	29-10-1996
		US 5505730 A	09-04-1996
		AU 2871795 A	19-01-1996
		NL 1000670 C	22-04-1996
		NL 1000670 A	27-12-1995
		US 6024743 A	15-02-2000
		US 6006755 A	28-12-1999
		US 6009877 A	04-01-2000
		US 6056744 A	02-05-2000
		US 6044846 A	04-04-2000
		US 6002968 A	14-12-1999
		WO 9600041 A	04-01-1996
		US 5681308 A	28-10-1997
		US 5769846 A	23-06-1998
		US 5964755 A	12-10-1999
		AU 707548 B	15-07-1999
		AU 2998195 A	19-01-1996
		CA 2193964 A	04-01-1996
		EP 0767629 A	16-04-1997
		WO 9600042 A	04-01-1996
		US 5827273 A	27-10-1998
		US 5800429 A	01-09-1998
		US 5746224 A	05-05-1998
		US 5823197 A	20-10-1998
		US 5843077 A	01-12-1998

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)